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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/345,148	06/30/1999	ANDREW H. SEGAL	3378/80490	9870

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/345,148	SEGAL, ANDREW H.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-16,19-68,70 and 71* is/are pending in the application.

4a) Of the above claim(s) *15,16,19,20,27 and 30-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 3-14, 21-26, 28-29, 70-71* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, field 10/12/06, has been entered and is acknowledged.

Claims 1, 3-16, 19-68 and 70-71 are pending.

Claims 2, 17-18 and 69 have been canceled.

Claims 15-16, 19-20, 27 and 30-68 have been withdrawn from consideration as being drawn to non-elected inventions or species.

As indicated in applicant's amendment, filed 10/12/06:
As currently amended, the instant claims relate to a method for vaccinating a mammal against an antigen by administering a composition comprising a cell that bears the antigen and an exogenous engineered ligand for CD40 (the term "exogenous" is defined on page 9 of the specification and the term "engineered ligand for CD40 is defined on page 10 of the specification). The engineered ligand for CD40 comprises a ligand for CD40 and a heterologous moiety that binds to the cell when the engineered ligand for CD40 is admixed with the cell.

The following is noted.

"Exogenous opsonin", "antigen", "cytokine", or "ligand for CD40" refers to an opsonin, antigen, cytokine of ligand for CD40 which is introduced from or produced outside the cell."
See page 10, paragraph 1 of the Substitute Specification, filed 4/10/03.

"The term "ligand for CD40" refers to a molecule that can bind to CD40 with an affinity at least in the micromolar range. An "engineered ligand for CD40" is a ligand for CD40 that comprises a heterologous cell membrane binding moiety"
See page 11, paragraph of the Substitute Specification, filed 4/10/03.

As noted throughout the prosecution of this application, the nature, metes and bounds and scope of the claimed composition has been the subject of the subject of the rejections of record and applicant's responses

Therefore, it remains unclear
whether the cell is *a recombinant cell expressing the antigen AND "the engineered ligand for CD40"* is a ligand for CD40 that comprises a heterologous cell membrane binding moiety",
whether the cell is *a non-recombinant cell expressing the antigen AND wherein the "engineered ligand for CD40" is a ligand for CD40 that comprises a heterologous cell membrane binding moiety" AND is associated with the cell via non-recombinant means* OR
whether the cell is a non-recombinant cell expressing the antigen AND the "engineered ligand for CD40" is a ligand for CD40 that comprises a heterologous cell membrane binding moiety" is a separate element from the cell.

Therefore, the following Species Election has been set forth.

The examiner apologizes for any inconvenience to applicant in this matter. However, the clarity of the "composition" utilized in the claimed methods has been ill-defined or subject to various interpretations.

Again, applicant is invited to amend the claims to particularly point out and distinctly claim the subject matter which applicant regards as the invention so that the ordinary artisan would have been apprised of the scope or metes and bounds of the claimed invention.

2. This application contains claims directed to the following patentably distinct species of the claimed "composition comprising a cell and an exogenous engineered ligand for CD40 wherein said cell comprises said antigen, wherein said engineered ligand for CD40 comprises a ligand for CD40, and a moiety heterologous to said ligand for CD40, wherein said moiety binds to said cell when said engineered ligand for CD40 is mixed with said said cell selected from:

A) a cell comprises the antigen and the cell is *a recombinant cell which has been engineered to express the engineered ligand for CD40, which comprises a ligand for CD40 and a moiety heterologous to said ligand for CD40*, wherein said moiety binds to said cell;

B) a cell comprises the antigen and the cell is *a non-recombinant cell* and wherein the engineered ligand for CD40, which comprises a ligand for CD40 and a moiety heterologous to said ligand for CD40, wherein said moiety binds to said cell is a *separate element but has been admixed* with the non-recombinant cell comprising an antigen and the cell, antigen and the engineered ligand and moiety are *all combined prior to administration*, OR

C) a cell comprises the antigen and the cell is a *non-recombinant cell* and the engineered ligand for CD40 comprises a ligand for CD40, and a moiety heterologous to said ligand for CD40, wherein said moiety binds to said cell is *administered separately* from the cell comprising the antigen.

These species of compositions are distinct because their structures and physicochemical properties differ. Therefore, they are separate and patentably distinct species

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, claim 1 is generic.

As noted throughout the prosecution of this application, the nature, metes and bounds and scope of the claimed composition has been the subject of the subject of the rejections of record and applicant's responses.

However, the clarity of the "composition" utilized in the claimed methods has been ill-defined or subject to various interpretations.

As noted above, applicant is invited to amend the claims to particularly point out and distinctly claim the subject matter which applicant regards as the invention so that the ordinary artisan would have been apprised of the scope or metes and bounds of the claimed invention.

3. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, Ph.D., J.D.
Primary Examiner
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January 18, 2006